

## **AMENDMENTS TO THE CLAIMS**

**39. (New)** A method for producing an orally administrable edible agent of laminate film form, the method comprising:

forming a plurality of orally administrable edible agent layers, wherein each orally administrable edible agent layer has a predetermined thickness and is formed on a surface of a respective resin film by coating and drying;

joining together two orally administrable edible agent layers so that orally administrable edible agent layer surfaces face each other and the orally administrable edible agent layers are sandwiched between the resin films of the two orally administrable edible agent layers, and pressurizing the resin films at back surfaces by a pair of press rolls so as to bond the orally administrable edible agent layers together, wherein the orally administrable edible agent layers include the same ingredient or different ingredients; and

delaminating only one of the two resin films by conveying the two resin films sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls, and drawing only one of the two resin films sandwiching the bonded orally administrable edible agent layers in a direction different from the conveying direction along a peripheral surface of a delamination roll disposed in the conveying direction while continuously conveying the other resin film retaining the bonded orally administrable edible agent layers in the conveying direction.

**40. (New)** The method for producing an orally administrable edible agent of laminate film form according to claim 39, wherein the one resin film to be delaminated in said delaminating of only one of the two resin films is previously subjected to release treatment at least on a surface provided with the orally administrable edible agent layer.

**41. (New)** The method for producing an orally administrable edible agent of laminate film form according to claim 39, wherein said pressurizing of the resin films at back surfaces by the pair of press rolls comprises pressurizing the resin films at a pressure of 0.05 to 1.5 MPa.

**42. (New)** The method for producing an orally administrable edible agent of laminate

film form according to claim 39, wherein a temperature of the orally administrable edible agent layers is 50°C to 180°C during said joining together of the two orally administrable edible agent layers.

**43. (New)** The method for producing an orally administrable edible agent of laminate film form according to claim 42, further comprising:

cooling the bonded orally administrable edible agent layers to a temperature at least 10°C lower than the temperature of the orally administrable edible agent layers during said joining together of the two orally administrable edible agent layers, and such that the temperature of the cooled orally administrable edible agent layers is higher than 0°C, wherein said cooling of the bonded orally administrable edible agent layers occurs after said joining together of the two orally administrable edible agent layers and before said delaminating of only one of the two resin films.

**44. (New)** The method for producing an orally administrable edible agent of laminate film form according to claim 42, wherein each of the bonded orally administrable edible agent layers includes an edible thermoplastic substance.

**45. (New)** The method for producing an orally administrable edible agent of laminate film form according to claim 44, wherein the edible thermoplastic substance includes at least one selected from the group consisting of amylose, carboxymethyl cellulose potassium, carboxymethyl cellulose sodium, carboxymethyl cellulose calcium, alkyl ester alginate, sodium alginate, ethylcellulose, eudragit, carboxymethylcellulose, carboxymethyl starch, carboxymethyl cellulose, agar, gelatin, shellac, dextran, dextrin, starch, tragacanth, hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose, hydroxypropylmethylcellulose phthalate, polyvinylpyrrolidone, methacrylic acid copolymer, and methylcellulose phthalate.

**46. (New)** The method for producing an orally administrable edible agent of laminate

film form according to claim 39, wherein a thickness of each of the bonded orally administrable edible agent layers is 1 to 300  $\mu\text{m}$ .

**47. (New)** The method for producing an orally administrable edible agent of laminate film form according to claim 39, wherein the bonded orally administrable edible agent layers are self-supporting laminated films.

**48. (New)** The method for producing an orally administrable edible agent of laminate film form according to claim 47, further comprising:

delaminating the other resin film retaining the orally administrable edible agent layers so as to finally delaminate the resin films from the bonded orally administrable edible agent layers.

**49. (New)** A method for producing an orally administrable edible agent of laminate film form, comprising:

forming a plurality of orally administrable edible agent layers, wherein each orally administrable edible agent layer has a predetermined thickness and is formed on a surface of a respective resin film by coating and drying;

joining together first and second orally administrable edible agent layers so that orally administrable edible agent layer surfaces face each other and the orally administrable edible agent layers are sandwiched between corresponding first and second resin films of the first and second orally administrable edible agent layers, and pressurizing the resin films at back surfaces by a pair of press rolls so as to bond the orally administrable edible agent layers together, wherein the orally administrable edible agent layers include the same ingredient or different ingredients;

delaminating only one of the first and second resin films by conveying the first and second resin films sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls, and drawing only one of the first and second resin films sandwiching the bonded orally administrable edible agent layers in a direction different from the conveying direction along a peripheral surface of a

delamination roll disposed in the conveying direction while continuously conveying the other of the first and second resin films retaining the bonded orally administrable edible agent layers in the conveying direction;

joining together a third orally administrable edible agent layer and the bonded first and second orally administrable edible agent layers so that orally administrable edible agent layer surfaces face each other and the first, second and third orally administrable edible agent layers are sandwiched between a corresponding third resin film of the third orally administrable edible agent layer and the other of the first and second resin films retaining the bonded first and second orally administrable edible agent layers, and pressurizing the resin films at back surfaces by the pair of press rolls so as to bond the first, second and third orally administrable edible agent layers together, wherein the third orally administrable edible agent layer includes the same ingredient or different ingredients as that of the bonded first and second orally administrable edible agent layers; and

delaminating only one of the resin films sandwiching the bonded first, second and third orally administrable edible agent layers by conveying the resin films sandwiching the bonded first, second and third orally administrable edible agent layers in the substantially tangential direction at the pressurization zone of the pair of press rolls, and drawing only one of the resin films sandwiching the bonded first, second and third orally administrable edible agent layers in a direction different from the conveying direction along the peripheral surface of the delamination roll disposed in the conveying direction while continuously conveying the other of the resin films retaining the first, second and third orally administrable edible agent layers in the conveying direction.

**50. (New)** The method for producing an orally administrable edible agent of laminate film form according to claim 49, wherein the one resin film to be delaminated in said delaminating of only one of the first and second resin films is previously subjected to release treatment at least on a surface provided with the orally administrable edible agent layer.

**51. (New)** The method for producing an orally administrable edible agent of laminate

film form according to claim 49, wherein the one resin film to be delaminated in said delaminating of only one of the resin films sandwiching the bonded first, second and third orally administrable edible agent layers is previously subjected to release treatment at least on a surface provided with the orally administrable edible agent layer.

**52. (New)** The method for producing an orally administrable edible agent of laminate film form according to claim 49, wherein said pressurizing of the resin films in said joining together of the first and second orally administrable edible agent layers and in said joining together of the third orally administrable edible agent layer and the bonded first and second orally administrable edible agent layers comprises pressurizing the resin films at a pressure of 0.05 to 1.5 MPa.

**53. (New)** The method for producing an orally administrable edible agent of laminate film form according to claim 49, wherein a temperature of the orally administrable edible agent layers is 50°C to 180°C during said joining together of the first and second orally administrable edible agent layers and during said joining together of the third orally administrable edible agent layer and the bonded first and second orally administrable edible agent layers.

**54. (New)** The method for producing an orally administrable edible agent of laminate film form according to claim 49, wherein a thickness of each of the bonded first, second and third orally administrable edible agent layers is 1 to 300 µm.

**55. (New)** The method for producing an orally administrable edible agent of laminate film form according to claim 49, wherein the bonded first, second and third orally administrable edible agent layers are self-supporting laminated films.

**56. (New)** A method for producing an orally administrable edible agent of laminate film form, comprising:

forming a plurality of orally administrable edible agent layers, wherein each orally

administrable edible agent layer has a predetermined thickness and is formed on a surface of a respective resin film by coating and drying;

winding each of the orally administrable edible agent layers into a roll so as to form a plurality of rolled films;

unwinding and joining together two rolled films so that surfaces of the orally administrable edible agent layers of the two rolled films face each other and the orally administrable edible agent layers are sandwiched between the resin films of the two rolled films, and pressurizing the resin films at back surfaces by a pair of press rolls so as to bond the orally administrable edible agent layers together, wherein the orally administrable edible agent layers include the same ingredient or different ingredients; and

delaminating only one of the two resin films by conveying the two resin films sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls, and drawing only one of the two resin films sandwiching the bonded orally administrable edible agent layers in a direction different from the conveying direction along a peripheral surface of a delamination roll disposed in the conveying direction while continuously conveying the other resin film retaining the bonded orally administrable edible agent layers in the conveying direction.

**57. (New)** The method for producing an orally administrable edible agent of laminate film form according to claim 56, wherein the one resin film to be delaminated in said delaminating of only one of the two resin films is previously subjected to release treatment on both a front surface to provided with the orally administrable edible agent layer and an opposite back surface, and the other resin film on which the bonded orally administrable edible agent layers are to be retained in said delaminating of only one of the two resin films is previously subjected to release treatment at least on a back surface which is not to be provided with an orally administrable edible agent layer.

**58. (New)** The method for producing an orally administrable edible agent of laminate film form according to claim 56, wherein said pressurizing of the resin films at back surfaces by the pair of press rolls comprises pressurizing the resin films at a pressure of 0.05 to 1.5 MPa.

**59. (New)** The method for producing an orally administrable edible agent of laminate film form according to claim 56, wherein a temperature of the orally administrable edible agent layers is 50°C to 180°C during said joining together of the two rolled films.

**60. (New)** The method for producing an orally administrable edible agent of laminate film form according to claim 56, wherein a thickness of each of the bonded orally administrable edible agent layers is 1 to 300 µm.

**61. (New)** The method for producing an orally administrable edible agent of laminate film form according to claim 56, wherein the bonded orally administrable edible agent layers are self-supporting laminated films.

**62. (New)** A method for producing an orally administrable edible agent of laminate film form, comprising:

forming a plurality of orally administrable edible agent layers, wherein each orally administrable edible agent layer has a predetermined thickness and is formed on a surface of a respective resin film by coating and drying;

winding each of the orally administrable edible agent layers into a roll so as to form a plurality of rolled films;

unwinding and joining together first and second rolled films so that surfaces of corresponding first and second orally administrable edible agent layers of the first and second rolled films face each other and the orally administrable edible agent layers are sandwiched between corresponding first and second resin films of the first and second rolled films, and pressurizing the resin films at back surfaces by a pair of press rolls so as to bond the orally administrable edible agent layers together, wherein the orally administrable edible agent layers include the same ingredient or different ingredients;

delaminating only one of the first and second resin films by conveying the first and second resin films sandwiching the bonded orally administrable edible agent layers in a

substantially tangential direction at a pressurization zone of the pair of press rolls, and drawing only one of the first and second resin films sandwiching the bonded orally administrable edible agent layers in a direction different from the conveying direction along a peripheral surface of a delamination roll disposed in the conveying direction while continuously conveying the other of the first and second resin films retaining the bonded first and second orally administrable edible agent layers in the conveying direction;

winding the resin film retaining the bonded orally administrable edible agent layers into a roll;

unwinding and joining together a third rolled film and the roll having the bonded first and second orally administrable edible agent layers so that surfaces of a corresponding third orally administrable edible agent layer of the third rolled film and one of the first and second orally administrable edible agent layers face each other and the first, second and third orally administrable edible agent layers are sandwiched between a corresponding third resin film of the third rolled film and the other of the first and second resin films retaining the bonded first and second orally administrable edible agent layers, and pressurizing the resin films at back surfaces by the pair of press rolls so as to bond the first, second and third orally administrable edible agent layers together, wherein the third orally administrable edible agent layer includes the same ingredient or different ingredients as that of the bonded first and second orally administrable edible agent layers; and

delaminating only one of the resin films sandwiching the bonded first, second and third orally administrable edible agent layers by conveying the resin films sandwiching the bonded first, second and third orally administrable edible agent layers in the substantially tangential direction at the pressurization zone of the pair of press rolls, and drawing only one of the resin films sandwiching the bonded first, second and third orally administrable edible agent layers in a direction different from the conveying direction along the peripheral surface of the delamination roll disposed in the conveying direction while continuously conveying the other of the resin films retaining the bonded first, second and third orally administrable edible agent layers in the conveying direction.

**63. (New)** The method for producing an orally administrable edible agent of laminate

film form according to claim 62, wherein the one resin film to be delaminated in said delaminating of only one of the resin films sandwiching the bonded first, second and third orally administrable edible agent layers is previously subjected to release treatment on both a front surface to be provided with an orally administrable edible agent layer and an opposite back surface, and the other of the resin films on which the bonded first, second and third orally administrable edible agent layers are to be retained in said delaminating of only one of the resin films sandwiching the bonded first, second and third orally administrable edible agent layers is previously subjected to release treatment at least on a back surface which is not to be provided with an orally administrable edible agent layer.

**64. (New)** The method for producing an orally administrable edible agent of laminate film form according to claim 62, wherein the one resin film to be delaminated in said delaminating of only one of the first and second resin films is previously subjected to release treatment on both a front surface to be provided with an orally administrable edible agent layer and an opposite back surface, and the other of the resin films on which the bonded first and second orally administrable edible agent layers are to be retained in said delaminating of only one of the first and second resin films is previously subjected to release treatment at least on a back surface which is not to be provided with an orally administrable edible agent layer.

**65. (New)** The method for producing an orally administrable edible agent of laminate film form according to claim 62, wherein said pressurizing of the resin films in said joining together of the first and second rolled films and in said joining together of the third rolled film and the roll having the bonded first and second orally administrable edible agent layers comprises pressurizing the resin films at a pressure of 0.05 to 1.5 MPa.

**66. (New)** The method for producing an orally administrable edible agent of laminate film form according to claim 62, wherein a temperature of the orally administrable edible agent layers is 50°C to 180°C during said joining together of the first and second rolled films and during said joining together of the third rolled film and the roll having the bonded first and

second orally administrable edible agent layers.

**67. (New)** The method for producing an orally administrable edible agent of laminate film form according to claim 62, wherein a thickness of each of the bonded first, second and third orally administrable edible agent layers is 1 to 300 µm.

**68. (New)** The method for producing an orally administrable edible agent of laminate film form according to claim 62, wherein the bonded first, second and third orally administrable edible agent layers are self-supporting laminated films.

**69. (New)** A pressure bonding apparatus for producing an orally administrable edible agent of laminate film form, comprising:

a pair of press rolls arranged to draw two resin films, each of said resin films being provided with an orally administrable edible agent layer having a predetermined thickness on a surface thereof, such that orally administrable edible agent layer surfaces face each other and said orally administrable edible agent layers are sandwiched between said resin films, said pair of press rolls being further arranged to pressurize said resin films at back surfaces thereof so as to bond said orally administrable edible agent layers together;

a delamination roll having a diameter of 6 cm or less disposed at a position forward of said pair of press rolls in a conveying direction of said pair of press rolls and in a substantially tangential direction at a pressurization zone of said pair of press rolls;

a winding shaft arranged to draw and delaminate only one of said two resin films sandwiching said orally administrable edible agent layers conveyed from said pair of press rolls to said delamination roll in a direction different from the conveying direction from said pair of press rolls to said delamination roll, along a peripheral surface of said delamination roll; and

a conveyance mechanism arranged to convey the other of said two resin films, which retains said orally administrable edible agent layers, in the conveying direction from said pair of press rolls to said delamination roll.

**70. (New)** The pressure bonding apparatus for producing an orally administrable edible agent of laminate film form according to claim 69, wherein said delamination roll is rotatably disposed so as to rotate with movement of said one resin film.

**71. (New)** The pressure bonding apparatus for producing an orally administrable edible agent of laminate film form according to claim 69, wherein said winding shaft is disposed in a position so as to draw said one resin film at an angle of 45° or more relative to the conveying direction of said other of said two resin films with said delamination roll as a starting point.

**72. (New)** The pressure bonding apparatus for producing an orally administrable edible agent of laminate film form according to claim 69, further comprising:

a pair of unwinding rolls arranged to respectively feed said two resin films to said pair of press rolls; and

a winding roll arranged to wind up said other of said two resin films, which retains said orally administrable edible agent layers,

wherein said unwinding roll and said winding roll have substantially the same dimension and structure and are interchangeable.

**73. (New)** The pressure bonding apparatus for producing an orally administrable edible agent of laminate film form according to claim 69, further comprising:

a slitter arranged to cut said other of said two resin films, which retains said orally administrable edible agent layers, into narrow strips in parallel with the conveying direction; and

a plurality of winding reels arranged to wind up the narrow strips, respectively, each of said winding reels including a winding shaft portion and a flange portion,

wherein said plurality of winding reels are arranged so that said winding shaft portions are staggered in backward and forward directions without gaps, and so that said flange portions are aligned in the backward and forward directions.

**74. (New)** The pressure bonding apparatus for producing an orally administrable edible

agent of laminate film form according to claim 73, further comprising:

a shaft arranged to support said plurality of winding reels; and

frames arranged so as to support both ends of said shaft, respectively, wherein one end of said shaft can be supported so as to be cantilevered by one of said frames, and the other of said frames can be brought down and stood up.

**75. (New)** The pressure bonding apparatus for producing an orally administrable edible agent of laminate film form according to claim 73, further comprising:

a shaft arranged to rotatably support each of said winding reels; and

a spring disposed at one end of said shaft and biased toward an opposite end of said shaft, said spring being arranged such that side walls of each winding reel are pressed by said spring, and such that a biasing force of said spring causes rotation of the shaft to be transmitted to said winding reels.

**76. (New)** The pressure bonding apparatus for producing an orally administrable edible agent of laminate film form according to claim 69, further comprising:

a slitter arranged to cut said other of said two resin films, which retains said orally administrable edible agent layers, into narrow strips in parallel with the conveying direction, said slitter being switchable between an ON state in which said slitter cuts said other of said two resin films into narrow strips in parallel with the conveying direction, and an OFF state in which said other resin film passes through said slitter without being cut;

a shaft arranged to support a plurality of winding reels, said winding reels being arranged to wind up said narrow strips, respectively, from said slitter in the ON state; and

a winding roll arranged to wind up said other resin film conveyed by said conveyance mechanism through said slitter in the OFF state,

wherein said winding roll and said shaft that supports said plurality of winding reels are interchangeable.